Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 22, 2016 5:15 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - 6(a) -"minimum"

> (1) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.

A question has arisen about the word "minimum". The word is there in part because of the Wyeth case in which the Supreme Court ruled that a VT failure to warn case was NOT preempted even though the manufacturer complied with an FDA labeling requirement. The court said there was no preemptive conflict between an FDA minimum label and what the VT failure to warn law required. The other issue the word "minimum' addresses is the scenario in which EPA sets a labeling requirement based on incomplete or false information and the people harmed by the chemical involving the inadequate label seek to prove that the company should have done more and knew that this was the case, and bring the complaint under state tort law – "minimum" therefore avoids a regulatory compliance defense so the court's decision is about the merits and not the preemptive effect of the federal label. Just because a company didn't HAVE to include the information on the label doesn't mean that they shouldn't have included it, and doesn't mean that they shouldn't have known that harm could have arisen from the chemical substance, and they shouldn't be able to assert preemption in order to avoid having the case heard.

But concerns with the word 'minimum' have been articulated as a belief that it means that a state could ALWAYS exceed a federal minimum labeling standard. My response to this is that section 18 governs this, not the word "minimum". If the state labeling law is grandfathered, it is grandfathered. If the label is required under a state clean air law, it is excepted from preemption. And if the state requests and receives an 18a waiver, preemption for it is waived. I don't see how the word 'minimum' changes anything about the way section 18 governs what states can do and when.

Does EPA agree with my read or am I missing something?

Thanks
michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 10:08:57 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA on new House section 4

Michal - Currently we're working on the Senate counter to the House offer on section 4, and section 14 requests from Dimitri and Jonathan. Are you waiting for anything else from EPA? Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 05, 2016 6:06 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on new House section 4

ty

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 05, 2016 5:42 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on new House section 4

Michal,
The attached TA responds to the request for high level comments on the new House section 4 (4/4/16 version). Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, April 04, 2016 11:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: Section 4 - the House offer

Sven

I mentioned earlier tonight that the House sent a section 4 offer that I found very concerning. I turned the offer into a redline of tsca in order to illustrate to my colleagues what it would look like.

I don't need detailed TA on this, but would appreciate your high level reaction to it (after section 5, and tomorrow morning is fine).

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/9/2016 12:46:12 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on replacement parts

We did a little googling and found the "Complex Durable Goods Coalition"--basically auto-related companies.

On Apr 8, 2016, at 8:28 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 08, 2016 8:27 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on replacement parts

Michal,
We don't have a problem per se with the term, we just don't know what it would be interpreted to mean. Thanks, Sven

On Apr 8, 2016, at 7:34 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Does "complex durable" which was sent to us by the House today, work at all?

Michal Ilana Freedhoff, Ph.D.
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 08, 2016 5:41 PM

To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on replacement parts

Michal,
This TA responds to the request on replacement parts, the initial request and followup question are included below.

Here are some thoughts on possible alternatives to deal with the replacement parts issue. We're not sure if they would completely deal with the issues but may provide a basis for a solution.

The first combines elements of the durable goods approach, with language regarding the use of products outside the home, and a modification of the provision regarding goods used by children to narrow it somewhat:

(C) The Administrator shall exempt replacement parts that are components of durable goods, which are defined as goods that are designed to be used repeatedly and have a useful life of greater than one [could be three or other time period] year, that are used [intended to be used][primarily] outside a home and that are [designed] prior to the effective date of the rule for articles that are first manufactured prior to the effective date of publication in the Federal Register of the rule unless—

(i) The Administrator finds such replacement parts contribute significantly to the identified risk, including identified risk to potentially exposed or susceptible populations; or

(ii) The replacement part is a component of an article that is reasonably expected to be used primarily by children aged 12 years of age and younger.

Either alternatively or in conjunction with the above, one could add language establishing a criterion that it would create a significant burden on the manufacturer if the replacement part were not exempted.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 08, 2016 3:08 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA -replacement parts

As a follow up, do you think the term "complex durable goods" would work to exclude

- Things like replacement teething rings and high chair tray inserts
- Disposable razors, air fresheners and the like
- Replacement couch seat cushion covers

There are conflicting definitions of "durable" – one is a 1 year definition, one is a 3 year definition

Thanks
m
Michal Ilana Freedhoff, Ph.D.
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Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 06, 2016 2:48 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - replacement parts

Sven

A proposal is being floated as a potential solution to the replacement parts/designed by provision that would limit the provision's application to parts that are components of "durable goods" which is
"Durable goods," is a widely used term - adapted from 16 C.F.R. 802.1(d)* A good is "durable" if it is designed to be used repeatedly and has a useful life greater than one year.

I don't think this works as is – it may address a sub-set of the kid/infant products I've expressed concerns about, but doesn't address the couch seat cushion covers for obvious reasons.

But I am wondering whether there exists anything in regulation or SNUR/article precedent that your team can think up? we did work through some language months ago that related to the difficulty of re-designing articles of which the parts were a component, but that language was not accepted. I may tinker with it more as well, but in the meantime, can your team think of anything they've done before, even if not in the TSCA context, that would define a universe of articles/parts it applied to in a manner that limits/excludes some and keeps others?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
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202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 9:48:50 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on section 6

Ok - will relay that. Thanks,
Sven

On Apr 13, 2016, at 5:37 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

6 should not be so bad though – note that HLC seems to do all the conforming x-refs at the end. We thought 6 was ok.

It would be great to get pbt tonight and turn to 6 for tomorrow as early as you can.

Michal Ilana Freedhoff, Ph.D.
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Office of Senator Edward J. Markey
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Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 13, 2016 5:34 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA request on section 6

Michal- we can turnaround the new PBT request tonight. Okay if 6 and 14 follow tomorrow afternoon? 6 requires some work. Thanks,
Sven

On Apr 13, 2016, at 3:16 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Do PBT, 5, 6, THEN 14

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 13, 2016 3:15 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on section 6

Michal – thanks for the request on section 6. Timing? We've got PBT, 5 and 14 in the queue. Best, Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 13, 2016 3:13 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: section 6

Sven

This is HLC section 6. Pls take a look.

Thanks
M

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 11:41:37 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on legislative history

Michal – that's great news – timing on leg history items? Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 7:40 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA Request on legislative history

Yes - all caught up. Assuming next House doc may be an assembled bill, but we'll see.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, April 21, 2016 7:39 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on legislative history

Michal – will pass along the request to start working on clarifying legislative history. I think we are caught up with you on requests – yes? Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 7:36 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA Request on nomenclature language - followup

Thanks. When the drafting TA is done, can you suggest some legislative history clarification?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, April 21, 2016 7:34 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on nomenclature language - followup

Michal –
This TA responds to the followup question on nomenclature.

The answer to both of your questions is no. We continue to think, though, per the comment we sent on the draft earlier today, that it would be helpful to clarify your drafting intent in the final legislative history. The Senate conference report contains some confusing statements about continuing the current policy of "not requiring notification for variations in . . . mixtures", which (if unaddressed) could influence subsequent interpretation of the statutory mixture provision.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 6:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Sen. Markey TSCA TA Request on nomenclature language

Sven

Does the attached second document that includes language that was proposed to the House by the Senate 1) present any of the problems described in your attached TA document on the language the House proposed to the Senate or 2) require a savings clause to protect against any unintended consequences?

Thanks
Michal

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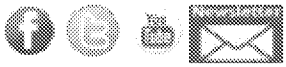

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 21, 2016 5:35 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on nomenclature language

Michal,
The attached TA responds to the request on nomenclature language (4-20).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 20, 2016 6:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: confidential draft

Pls review. Section 6 coming soon.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Wednesday, April 20, 2016 6:29 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick
Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"

- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) –
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26

- On page 12 – delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below.

''(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

-

On section 8:

Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations – if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

-

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule. Keep tiered testing, but tweak it:

''(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall *consider employing* a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first *considering* [conducting] screening-level testing.'';

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/3/2016 2:26:34 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: New Followup - Sen. Markey TSCA TA request on section 5 PBTs

Michal- we would like to call you on this. Are you available now? # to call?

On Mar 3, 2016, at 5:28 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

On this one (and again, pls rush this one - happy to do by call if easier. Thx.

- if we said something like "for a PBT chemical substance described in the 1999 document (or successor), the Administrator shall, in selecting among prohibitions.... and then keep meximum extent practicable"

1) it is my expectation that doing this could capture more PBTS - does the 1999 doc apply just to high PBTs?
2) does the 1999 doc include a scoring system?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, March 3, 2016 12:34 AM
To: Freedhoff, Michal (Markey)
Subject: Fwd: New Followup - Sen. Markey TSCA TA request on section 5 PBTs

Michal- TA on section 5 PBTs. Thanks,
Sven

I was responding to your earlier TA that I attached with the incoming question that said your current PBT policy from 1999 leads to more restrictive risk management than the 697 language. In thinking about a concern raised by an external stakeholder that applying a tsca workplan methods document to new chemicals may not make sense, I wondered if there was a way to strengthen the section 5 PBT provision by referencing the 1999 policy instead of the 2012 scoring document and maximum practicable.

Does that help you frame some drafting options?

As you point out, we said in earlier TA that "application of the New Chemical PBT policy. . . is likely to be more stringent than the risk management standard included in the Senate PBT provision -- 'reduce exposure to the maximum extent practicable'". On further reflection, we no longer believe this is true.

The Senate PBT new chemicals standard is not to reduce exposure to the maximum extent practicable; rather, it is to ensure the chemical is likely to meet the safety standard AND, IN ADDITION, to reduce exposure to the maximum extent practicable. Although TSCA section 5(e) does not contain an explicit standard for the restrictions EPA can impose through orders, we believe it is best interpreted as implicitly limiting the restrictions to those that are reasonably necessary to address the risk concerns that led EPA to conclude the chemical may present an unreasonable risk, and EPA has implemented section 5(e) with that understanding. The reason EPA in the new chemical PBT guidance prescribed ban pending upfront testing as the general response for new chemicals that exceed the upper threshold for persistence or bioaccumulation is that EPA believes such a restriction is generally necessary to protect against the potential unreasonable risk, given the uncertainty as to the impacts of the manufacture, processing and use of such chemicals, even at low levels, over time. We believe the same logic would lead to the conclusion that a ban pending upfront testing is necessary to ensure a new PBT chemical meeting one of these thresholds is likely to meet the safety standard under S 697.

Moreover, because a new chemical by definition has not been commercialized, EPA believes a ban pending upfront testing would generally be practicable, even if the exposure reduction provision were applicable.

We do not share the stakeholder's concerns regarding the applicability of the 2012 Workplan Methods Document in the new chemicals context. The reference in 5(d)(4)(D) of 697 requires EPA to apply only the portion of the 2012 Methods document related to identifying P, B, and T characteristics of a chemical, and we believe this process is equally applicable and appropriate for both new and existing chemicals.

Let us know if you would still like assistance in drafting language options to achieve a certain policy objective.

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 02, 2016 10:30 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA request on section 5 PBTs

Thanks

I was responding to your earlier TA that I attached with the incoming question that said your current PBT policy from 1999 leads to more restrictive risk management than the 697 language. In thinking about a concern raised by an external stakeholder that applying a tsca workplan methods document to new chemicals may not make sense, I wondered if there was a way to strengthen the section 5 PBT provision by referencing the 1999 policy instead of the 2012 scoring document and maximum practicable.

Does that help you frame some drafting options?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Wednesday, March 2, 2016 10:23 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on section 5 PBTs

Michal – please see the attached document in response to your TA request on PBTs. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, February 29, 2016 1:59 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA PBTs on New Chemicals

Sven:

Wanted to confirm EPA views of a proposed change to section 5 PBT language following on this older TA. Is the new alternative likely to result in a more stringent outcome than S 697? If not, can you suggest a tweak?
Thanks
Michal

Proposing to change from

D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment, reduce potential exposure to the substance to the maximum extent practicable.

To

D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—In selecting among prohibitions and other restrictions for a chemical substance that is a persistent and bioaccumulative substance, the Administrator shall act in a manner consistent with the TSCA Policy Statement on Persistent, Bioaccumulative and Toxic New Chemical Substances published by the Administrator in November 1999 (or a successor Policy Statement).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building

Washington, DC 20510
202-224-2742

Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 03, 2015 7:20 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA PBTs on New Chemicals

Michal,
This responds to your TA request on new chemical reviews. Please let me know if any additional questions Thanks,
Sven

Question: If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so, and b) how long would scoring take (days, weeks, months, etc?)

a) **Yes, EPA would be able to score new chemicals in the same way it scores chemicals pursuant the TSCA Work Plan Methods document, and**
b) **The time to do so would not extend the PMN process beyond allotted 90-day deadline.**

However, we'd note that application of the New Chemical PBT policy referenced in previous TA is likely to be more stringent than the risk management standard included in the Senate PBT provision - "reduce exposure to the maximum extent practicable"

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on PBTs

Quick follow up for you – would be great to get this by 5 pm or shortly thereafter. If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so and b) how long would scoring take (days, weeks, months, etc?)

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
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202-224-2742

Connect with Senator Markey

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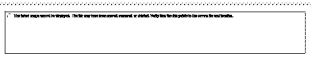
From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 03, 2015 2:04 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on PBTs

Michal,

This responds to your TA requests on PBT determination and the follow on question about "maximum extent practicable".

1. Section 5 PBT language in S 697 requires EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

EPA currently reviews and categorizes new chemicals for persistence, bioaccumulation, and toxicity (PBT) characteristics under section 5 of TSCA in accordance with a policy statement published in 1999. A copy of the proposed and final policy is available on our website here. New chemicals are not currently scored "pursuant to" the 2012 Work Plan Chemicals Methods document. Because the language in 5(d)(4)(D) does not require a mandatory scoring of new chemicals for P or B pursuant to the Work Plan Chemicals Methods document, one possible outcome is that EPA never makes such a determination, and the specified risk management standard is never invoked.



Policy Statement on a New Chemicals Category for ...

On November 4, 1999, EPA issued its final policy statement (64 FR 60194) on a category for Persistent Bioaccumulative and Toxic new chemicals.

Read more...

2. Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

As a purely linguistic matter, we do not see a significant difference between "to the extent practicable" and "to the maximum extent practicable" – the concept of "maximum" seems be implied in the first formulation. That having been said, arguments could certainly be raised that Congress' choice of the less explicit House formulation over the Senate formulation (in sections 5(d)(4)(D) and 6(d)(2)(B) of TSCA as modified by the Senate bill), indicates a choice to adopt a less demanding understanding of the extent to which EPA is required or authorized to reduce PBT exposure.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:44 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: Quick follow on on PBTs

Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: November 24, 2015 at 10:11:33 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: PBT question
Sven

Question for you – section 5 PBT language in S 697 require EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/9/2016 12:26:52 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on replacement parts

Michal,
We don't have a problem per se with the term, we just don't know what it would be interpreted to mean. Thanks,
Sven

On Apr 8, 2016, at 7:34 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Does "complex durable" which was sent to us by the House today, work at all?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 08, 2016 5:41 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on replacement parts

Michal,
This TA responds to the request on replacement parts, the initial request and followup question are included below.

Here are some thoughts on possible alternatives to deal with the replacement parts issue. We're not sure if they would completely deal with the issues but may provide a basis for a solution.

The first combines elements of the durable goods approach, with language regarding the use of products outside the home, and a modification of the provision regarding goods used by children to narrow it somewhat:

(C) The Administrator shall exempt replacement parts that are components of durable goods, which are defined as goods that are designed to be used repeatedly and have a useful life of greater than one [could be three or other time period] year, that are used [intended to be used][primarily] outside a home and that are [designed] prior to the effective date of the rule for articles that are first manufactured prior to the effective date of publication in the Federal Register of the rule unless—

(i) The Administrator finds such replacement parts contribute significantly to the identified risk, including identified risk to potentially exposed or susceptible populations; or

(ii) The replacement part is a component of an article that is reasonably expected to be used primarily by children aged 12 years of age and younger.

Either alternatively or in conjunction with the above, one could add language establishing a criterion that it would create a significant burden on the manufacturer if the replacement part were not exempted.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 08, 2016 3:08 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA -replacement parts

As a follow up, do you think the term "complex durable goods" would work to exclude

- Things like replacement teething rings and high chair tray inserts
- Disposable razors, air fresheners and the like
- Replacement couch seat cushion covers

There are conflicting definitions of "durable" – one is a 1 year definition, one is a 3 year definition

Thanks
m
Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
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202-224-2742

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 06, 2016 2:48 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - replacement parts

Sven

A proposal is being floated as a potential solution to the replacement parts/designed by provision that would limit the provision's application to parts that are components of "durable goods" which is
"Durable goods," is a widely used term - adapted from 16 C.F.R. 802.1(d)* A good is "durable" if it is designed to be used repeatedly and has a useful life greater than one year.

I don't think this works as is – it may address a sub-set of the kid/infant products I've expressed concerns about, but doesn't address the couch seat cushion covers for obvious reasons.

But I am wondering whether there exists anything in regulation or SNUR/article precedent that your team can think up? we did work through some language months ago that related to the difficulty of re-designing articles of which the parts were a component, but that language was not accepted. I may tinker with it more as well, but in the meantime, can your team think of anything they've done before, even if not in the TSCA context, that would define a universe of articles/parts it applied to in a manner that limits/excludes some and keeps others?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 9:34:12 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on section 6

Michal- we can turnaround the new PBT request tonight. Okay if 6 and 14 follow tomorrow afternoon? 6 requires some work. Thanks,
Sven

On Apr 13, 2016, at 3:16 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Do PBT, 5, 6, THEN 14

Michal Ilana Freedhoff, Ph.D.
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Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 13, 2016 3:15 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on section 6

Michal – thanks for the request on section 6. Timing? We've got PBT, 5 and 14 in the queue. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 13, 2016 3:13 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: section 6

Sven

This is HLC section 6. Pls take a look.

Thanks
M

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 11:38:52 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on legislative history

Michal – will pass along the request to start working on clarifying legislative history. I think we are caught up with you on requests – yes? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 7:36 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA Request on nomenclature language - followup

Thanks. When the drafting TA is done, can you suggest some legislative history clarification?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, April 21, 2016 7:34 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on nomenclature language - followup

Michal –
This TA responds to the followup question on nomenclature.

The answer to both of your questions is no. We continue to think, though, per the comment we sent on the draft earlier today, that it would be helpful to clarify your drafting intent in the final legislative history. The Senate conference report contains some confusing statements about continuing the current policy of "not requiring notification for variations in . . . mixtures", which (if unaddressed) could influence subsequent interpretation of the statutory mixture provision.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 6:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Sen. Markey TSCA TA Request on nomenclature language

Sven

Does the attached second document that includes language that was proposed to the House by the Senate 1) present any of the problems described in your attached TA document on the language the House proposed to the Senate or 2) require a savings clause to protect against any unintended consequences?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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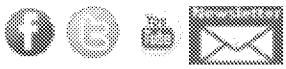

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 21, 2016 5:35 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on nomenclature language

Michal,
The attached TA responds to the request on nomenclature language (4-20).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 20, 2016 6:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: confidential draft

Pls review. Section 6 coming soon.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Wednesday, April 20, 2016 6:29 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick
Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"

- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) –
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26
- On page 12 – delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below.
"(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

-

On section 8:
Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations – if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

-

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule. Keep tiered testing, but tweak it:

''(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall *consider employing* a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first *considering* [conducting] screening-level testing.'';

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/20/2016 1:43:43 AM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Sen. Udall TSCA TA on Mixed confidential section

Jonathan,
Is this when I say that is your third wish? I'll pass along the call request - are you thinking 9:00am or so?
Thanks,
Sven

On Apr 19, 2016, at 9:42 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

And perhaps a call on this tomorrow morning.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Black, Jonathan (Tom Udall)
Sent: Tuesday, April 19, 2016 9:39 PM
To: Kaiser, Sven-Erik
Subject: Re: Sen. Udall TSCA TA on Mixed confidential section

Also: what would be lost, if anything, by deleting this paragraph?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Tuesday, April 19, 2016 9:35 PM
To: Black, Jonathan (Tom Udall)
Subject: Sen. Udall TSCA TA on Mixed confidential section

Jonathan,
Got it - checking. Thanks,
Sven

On Apr 19, 2016, at 9:30 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Can we get epa TA drafting assistance on HLC's section 14,

14(b)(1) the mixed confidential section?

we'd like to see how you would do it?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/17/2016 1:28:15 PM
To: Cohen, Jacqueline [jackie.cohen@mail.house.gov]
Subject: Notification: EPA Announces Public Meeting on TSCA New Chemicals Review - December 14

Jacqueline,
Heads up that EPA is holding a meeting to update the public on changes to the TSCA New Chemicals Review Program on Weds, Dec 14. EPA will describe the review process for new chemicals under the amended statute, as well as discuss issues, challenges, and opportunities that the agency has identified in the first few months of implementation. Interested parties will have the opportunity to provide input on their experiences with the New Chemicals Review Program, including submittal of pre-manufacture notices (PMNs), microbial commercial activities notices (MCANs), and significant new use notices (SNUNs), under section 5 of the law. Information obtained during this meeting and from submitted written comments will be considered as EPA implements the new requirements and increases efficiency in its review process under TSCA.

Register for the meeting in advance: We ask that you please register for this meeting by December 13, 2016.

Date and Time: Wednesday, December 14, 2016, from 9:00 a.m. to 12:00 p.m.

Location: The Ronald Reagan Building and International Trade Center, Polaris Room, 1300 Pennsylvania Avenue Northwest, Washington, DC 20004

Docket number to submit written comments: EPA-HQ-OPPT-2016-0658 (Docket will be open prior to and remain open after the meeting.)

We're working on your request on the TSCA new chemicals program and I expect a response shortly. Please let me know if you would like a briefing on new chemicals program prior to or in connection with the public meeting. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 11:54:26 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on replacement parts

Got it - thanks

On Apr 8, 2016, at 7:34 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Does "complex durable" which was sent to us by the House today, work at all?

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Sent: Friday, April 08, 2016 5:41 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on replacement parts

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(i) The Administrator finds such replacement parts contribute significantly to the identified risk, including identified risk to potentially exposed or susceptible populations; or

(ii) The replacement part is a component of an article that is reasonably expected to be used primarily by children aged 12 years of age and younger.

Either alternatively or in conjunction with the above, one could add language establishing a criterion that it would create a significant burden on the manufacturer if the replacement part were not exempted.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 08, 2016 3:08 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA -replacement parts

As a follow up, do you think the term "complex durable goods" would work to exclude

- Things like replacement teething rings and high chair tray inserts
- Disposable razors, air fresheners and the like
- Replacement couch seat cushion covers

There are conflicting definitions of "durable" – one is a 1 year definition, one is a 3 year definition

Thanks
m
Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 06, 2016 2:48 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - replacement parts

Sven

A proposal is being floated as a potential solution to the replacement parts/designed by provision that would limit the provision's application to parts that are components of "durable goods" which is
"Durable goods," is a widely used term - adapted from 16 C.F.R. 802.1(d)* A good is "durable" if it is designed to be used repeatedly and has a useful life greater than one year.

I don't think this works as is – it may address a sub-set of the kid/infant products I've expressed concerns about, but doesn't address the couch seat cushion covers for obvious reasons.

But I am wondering whether there exists anything in regulation or SNUR/article precedent that your team can think up? we did work through some language months ago that related to the difficulty of re-designing articles of which the parts were a component, but that language was not accepted. I may tinker with it more as well, but in the meantime, can your team think of anything they've done before, even if not in the TSCA context, that would define a universe of articles/parts it applied to in a manner that limits/excludes some and keeps others?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/3/2016 1:28:14 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: SEPW TSCA TA on Judicial Review

Dimitri - this TA responds to the request on section 19 judicial review.

QUESTIONS: As I mentioned on the phone here are two possible tweaks to Senate section 19 that could resolve some perceived ambiguity in what parts of section 6 determinations are subject to the substantial evidence standard. Any TA on whether these make sense, seem duplicative, etc.

Insert a parenthetical in the proposed amendments to section 18(c)(1)(B)(i) to read:

"section 4(a), 6(d) (including review of an associated determination under section 6(c)(1)(B)), or 6(g), or an order under section 6(c)(1)(A)."

"section 4(a), 6(d) (including review of an associated determination under section 6(c)(1)(B), consistent with section 6(f)), or 6(g), or an order under section 6(c)(1)(A)."

RESPONSE: We presume you're referring to an amendment to 19(c)(1)(B)(i), as found in the bill as it passed the Senate. Note that the reference to 6(g) is incorrect. It should be 6(h) (PCB rules). Note also that there several places where conforming changes in 19(c) are needed to make clear that orders under 6(c)(1)(A), not just rules, can be subject to substantial evidence review.

The changes you suggest are unnecessary. We do not believe there is a credible argument under the bill that the safety determination preceding a rulemaking under section 6(d) is reviewable under a standard other than substantial evidence, since the safety determination would be part of the record of the rulemaking, and since "positive" safety determinations are clearly subject to substantial evidence review under 19(c)(1)(B)(i). And, in general, we believe that adding unnecessary language has the potential to cause confusion.

That said, option 1 is largely harmless if properly edited. To be consistent with the overall structure of the Senate bill, it should read: "section 4(a), 6(d) (including review of **the** associated determination under section 6(c)(1)(B)), or 6(**h**), or an order under section 6(c)(1)(A)." The definite article is to maintain consistency with 6(f)(2), which refers to "the associated safety assessment and safety determination." Referring to "an associated determination" could give rise to arguments that other safety determinations (i.e., other than the one that gave rise to the risk management rule) are sufficiently associated with the rule that they should be reviewed as part of the risk management rule.

Option 2 introduces some further potential for confusion. It suggests the possibility that some review of "[the] associated determination under section 6(c)(1)(B)" might not actually be "consistent with section 6(f)," and so therefore wouldn't be reviewed under the substantial evidence standard. We can't imagine that scenario, since reviewing the associated determination under 6(c)(1)(B), under the substantial evidence standard, seems inherently consistent with section 6(f). But the language seems to be suggesting an inconsistency might exist, and that the reader needs to be watching out for it.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Thursday, March 31, 2016 6:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Judicial Review

Sven,

As I mentioned on the phone here are two possible tweaks to Senate section 19 that could resolve some perceived ambiguity in what parts of section 6 determinations are subject to the substantial evidence standard. Any TA on whether these make sense, seem duplicative, etc.

Insert a parenthetical in the proposed amendments to section 18(c)(1)(B)(i) to read:
"section 4(a), 6(d) (including review of an associated determination under section 6(c)(1)(B)), or 6(g), or an order under section 6(c)(1)(A)."

"section 4(a), 6(d) (including review of an associated determination under section 6(c)(1)(B), consistent with section 6(f)), or 6(g), or an order under section 6(c)(1)(A)."

Thanks

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 11:34:23 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on nomenclature language - followup

Michal –
This TA responds to the followup question on nomenclature.

The answer to both of your questions is no. We continue to think, though, per the comment we sent on the draft earlier today, that it would be helpful to clarify your drafting intent in the final legislative history. The Senate conference report contains some confusing statements about continuing the current policy of "not requiring notification for variations in . . . mixtures", which (if unaddressed) could influence subsequent interpretation of the statutory mixture provision.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 6:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Sen. Markey TSCA TA Request on nomenclature language

Sven

Does the attached second document that includes language that was proposed to the House by the Senate 1) present any of the problems described in your attached TA document on the language the House proposed to the Senate or 2) require a savings clause to protect against any unintended consequences?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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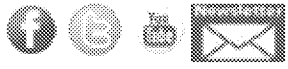

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 21, 2016 5:35 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on nomenclature language

Michal,
The attached TA responds to the request on nomenclature language (4-20).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 20, 2016 6:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: confidential draft

Pls review. Section 6 coming soon.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Wednesday, April 20, 2016 6:29 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick
Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"

- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) –
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26

- On page 12 – delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below.

''(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

-

On section 8:

Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations – if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

-

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule. Keep tiered testing, but tweak it:

''(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall *consider employing* a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first *considering* [conducting] screening-level testing.'';

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/12/2016 1:24:29 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on section 5 "may present"

Michal, checking. Availability today for a call? Thanks,
Sven

On Mar 12, 2016, at 6:29 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Not sure if this is best left for a call rather than an email exchange. Your drafting suggestions make sense to me.

But I'm also interested in more of a policy discussion about what dropping the requirement that EPA explicitly make an "unlikely to present" (ie the (2)(B) finding) means.

There appear to be very strong and diverse views on this point, which include:

- it is impossible to make such a finding about a new chemical and doing so would provide people with a false sense of safety related to the chemical
- it is impossible to make such a finding about a new chemical and requiring EPA to do so would result in no new chemicals ever being allowed onto the market
- removing the requirement to make such a finding would represent an enormous concession and policy shift from current senate position because every chemical should be deemed safe before it enters the marketplace

The option we are discussing says "tell me if it is unsafe. If it is, fix the problem. If you don't know, find out and then fix the problem if there is one". To me, inherent and embedded in that is a requirement that EPA make a safety determination - safe or unsafe- even if we are not explicitly requiring epa to pronounce a new chemical to be safe. Others disagree with me completely. I'd like EPA's views.

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, March 11, 2016 9:24 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 5 "may present"

Michal, this responds to your YA request in section 5 determinations. Please see the attached TA along with the comments below.

Option #1 … This won't work well. If EPA has a basis to say that a chemical substance "may present" an UR,

there is no direction about whether to make that finding or whether to just give the chemical a pass, which is an alternative option. The intention is presumably that EPA can make the "may commence" finding only if EPA has no basis to make the "may present" finding, but the language does not say that. This option also presents some of the issues identified for option 2.

Option 2 seems to provide clearer direction but raises some issues, identified, with suggested possible fixes, in the attachment.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/11/2016 7:19:59 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on CBI and Chem ID
Attachments: Markey.TSCA TA.CBI and Chem ID.docx

Michal,
This responds to the TA request on Chem ID and health and safety study information. Note that all of our drafting suggestions are on p.1 of the attachment.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, April 11, 2016 9:23 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on Chem ID

Sven

Getting back to this question from a different direction – your TA below says that there is a 3rd basis for withholding chemID from HS: "where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study."

We have the pre-NOC exclusion in current senate 14

> (i) The specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5.

I am wondering if "if the specific identity is not necessary to interpret the HS study" is something that I should be exploring in addition to the other ideas for inclusion alongside process and concentration/proportion. To that end, is there an easy way that you could provide me with some statistics/#s along the following lines (approximate #s ok)

1- How many chemID CBI claims are there generally? Per year?
2- How many chem IDs are withheld (both generally and per year) from HS studies because releasing would reveal
    a. Process

b. Concentration/proportion
c. Pre-NOC AND info not necessary

If this is impossible to figure out in a quick timeframe let me know and maybe we can figure out some other way to answer my question, which is, generally, "what is the actual impact of adding the specific identity is not necessary to interpret the health and safety study" under this EPA's practice.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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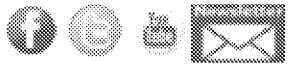

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Saturday, April 09, 2016 12:19 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Chem ID

Michal,
This TA responds to the request on chem ID.

Your two emails seem to be asking questions in different directions: the first seems to be asking whether another basis could be added for allowing the withholding of chem id *in health and safety studies* (presumably something industry would want), and the second seems to be asking the very different question of whether there should be more stringent expiration or voiding conditions for chem id *outside the context of health and safety studies* than for other CBI (presumably something the NGOs would want).

Re your first question: although the statute allows for withholding of chem ID (or other info) in health and safety studies only on two bases (reveals process information of proportions of a mixture), EPA regulations allow withholding of specific chem ID on a third basis: where the chemical has not been commercialized and the specific identity is not necessary to interpret the health and safety study. That kind of provision could be codified in the bill.

Re your second question: The idea sounds like a beefing up of sec 14(c)(3) of the Senate offer, which presumptively voids CBI claims for chem ID and other information elements following a ban of a chemical. The triggering event for that provision could be moved up to the finding of unreasonable risk.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 9, 2016 at 11:20:40 AM EDT

To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request on ChemID

As part of your thought process here, and perhaps as an alternative option, let's think about a way where if chemID is kept CBI it goes public if a) epa makes a section 6 or 7 unreasonable risk finding about it and b) it has to be re-substantiated every 5/10 years with reasonable potential of an unreasonable risk being one of the things EPA has to consider.

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

On Apr 9, 2016, at 5:40 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:
Good morning

We increasingly hear that "molecular structure" is a huge threshold issue for the House. It is for us too. I'm trying to learn more about the history here and also see if there exists middle ground - something akin to a 3rd condition for when chemID is withheld, like "keep molecular structures secret if X or Y, or unless X or Y". I'm not sure if a space like this exists for either side, but thought perhaps looking towards the recent decisions by EPA on why it did or did not release molecular structure could be useful.

Can you put together background materials or suggestions if you have any? Doesn't have to be before 1, but would be helpful if it was before 5 or 6 pm so I can review tonight as part of some of the other prep work I'm planning.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy position of the agency and the administration on the bill, the draft language and the comments.

SEC. 14. CONFIDENTIAL INFORMATIONDISCLOSURE OF DATA.

x-refs not all conformed pending review of text

(a) IN GENERAL.—Except as provided in ~~by sub~~this section ~~(b)~~, the Administrator shall not disclose ~~any~~ information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section—

(1) that is reported to, or otherwise obtained by, the Administrator ~~(or any representative of the Administrator)~~ under this Act~~, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States, except that such information~~—; and

(2) for which the requirements of subsection (c) are met.

In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

(b) Information Not Protected From Disclosure.—

(1) DATA FROM HEALTH AND SAFETY STUDIES.— Subsections (a) does not prohibit the disclosure of

(A) any health and safety study which is submitted under this Act with respect to—

(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, ~~or~~

(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

(2) (A) Subject to (2)(B), the specific identity of a chemical substance that is the subject of a health and safety study that satisfies the conditions of (1)(A) shall not be disclosed, if such chemical identity is otherwise eligible for protection under this section, unless the Administrator determined under section 6xxx that the chemical substance presents or will present an unreasonable risk of injury to health or the environment or the Administrator initiates an action with respect to the chemical substance under section 7(a).

(B)(i) The duration of protection for the specific identity of a chemical substance described in (2)(A) and the renewal of such protection shall be governed by section 14(e), except that the duration of protection shall be 5 years.

~~(B)~~ (ii) The Administrator may, in limited circumstances, review a claim for protection of the identity of a chemical described in (2)(A) if the Administrator determines that disclosure of such specific chemical identity would assist with the identification or remediation of an environmental hazard or exposure, or the diagnosis or treatment of an adverse health effect, that might be caused by the chemical substance.

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

Commented [A1]: Moved per EPA TA to appear where it should.

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Commented [A2]: We thought it simpler to put all the provisions in (b)(1), rather than dividing them between (b) and (e), so this is all of our suggested text to accomplish what we understand to be your objective. Some further scrubbing of this would probably be in order – eg, to make sure the reference to (e) in (B)(i) fully works -- but we first wanted to get a sense of whether this approach works.

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Commented [A3]: Per request, we have included this proviso. Note, though, that this is a good example of the general issue we have raised as to whether the grounds for review of CBI claims in section 14(e) should be viewed as exclusive or merely exemplary. If this language is added here, it will clearly mean that EPA cannot, outside of this context, review (ie, internally examine) a CBI claim even if the Agency determines that the information will assist with the activities identified.

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